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JAN 2 0 2011

510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM: Ortho Solutions Limited
West Station Buisness Park
Spital Road
Maldon
ESSEX, CM9 6FF
United Kingdom

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372
Telephone No: 952-492-5858
E-mail: allippincott@msn.com

DATE: September 13, 2010

TRADE NAME: Ortho Solutions Sterile Drill Bits

COMMON NAME: Sterile Single-Use – Drill Bits

CLASSIFICATION: Surgical instrument motors and accessories/attachments *(see 21 CFR Sec. 878.4820)*

DEVICE PRODUCT CODE: **HWE**

SUBSEQUENT PRODUCT CODE: **GFF, HSZ, GFA**

SUBSTANTIALLY EQUIVALENT DEVICES Synthes Sterile Drill Bits **(K962913)**

DEVICE DESCRIPTION: All Ortho Solutions Sterile Single-Use Drills Bits are manufactured from common Stainless Steel materials that are either cold-worked or heat treated for hardness cutting durability and for corrosion resistance. Ortho Solutions sterile drill bits are available in various sizes and lengths, have a fluted design, and are either in a solid or cannulated form and may be calibrated. The Ortho Solutions drill bits have various end coupling mechanisms. Ortho Solutions drill bits will be provided to the user 'sterile'. Gamma Radiation will be used to sterilize the device.

INTENDED USE: Ortho Solutions sterile drill bits are intended to bore a hole into bone for insertion of a screw, wire, cable, plate, pin, bolt, etc.

Ortho Solutions Limited - K102743 510(k) Summary:

EQUIVALENCE:	The Ortho Solutions Sterile Drill Bits are Substantially Equivalent (SE) to the Synthes K962913 Sterile Drill Bits.
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS	The Ortho Solutions Sterile Drill Bits are identical in Material, Geometry Design/Markings, and Indications to the Synthes Sterile Drill Bits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ortho Solutions Limited
% Engineering Consulting Services, Inc.
Mr. Al Lippincott
3150 East 200th Street
Prior Lake, Minnesota 55372

JAN 20 2011

Re: K102743
Trade/Device Name: Ortho Solutions Sterile Drill Bits
Regulation Number: 21 CFR 878.4820
Regulation Name: Surgical instrument motors and accessories/attachments
Regulatory Class: Class II
Product Code: HWE, GFF, HSZ, GFA
Dated: December 20, 2010
Received: December 27, 2010

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ORTHO SOLUTIONS

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www.orthosolutions.com

Indications for Use

510(k) NUMBER: **K102743**

DEVICE NAME: **Ortho Solutions Sterile Drill Bits**

INDICATIONS FOR USE:

Ortho Solutions sterile drill bits are intended to bore a hole into bone for insertion of a screw, wire, cable, plate, pin, bolt, etc.

Mark R Poehler for mkn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102743

Prescription Use ___X___ AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)